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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,177	12/21/2001	Craig P. Hunter	42697.122US2	7824
23483	7590	05/04/2004	EXAMINER	
HALE AND DORR, LLP			TUNG, JOYCE	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	

1637

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,177

Applicant(s)

HUNTER ET AL.

Examiner

Joyce Tung

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-58 and 67-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 53-58 and 67-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>04/21/2004</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 19, 2004 has been entered.

Now claims 53-58 and 67-80 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 53, 56-57, 70-73, 76-77, and 79-80 are rejected under 35 U.S.C. 102(e) as being by Pelletier et al. (US 2002/0119467 A1, issued August 29, 2002).

Pelletier et al. disclose an improved method of cDNA synthesis. The improvement is consisting in an addition of a RNA binding protein to the nucleic acid polymerization mixture comprising the reverse transcriptase. The addition of the RNA binding protein enables an increase of the processivity of the reverse transcriptase and a significant increase in the production of full length of cDNAs (See the Abstract and claim 6). The RNA binding protein binds to single stranded and/or double stranded RNA in a non-sequence specific manner (See pg.

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3, paragraph 0036). The single strand binding protein is rec a protein, single strand DNA binding protein and gene 32 product of T4 bacteriophage (T4gp32) (See pg. 3 paragraph 0028). First strand RT reactions were performed with oligo d (T) (See pg. 5, paragraph 0061). The length of the first strand is about 920 bases (See pg. 5, paragraph 0061). The invention has an impact on the benefit of T7 RNA polymerase (See pg. 3, paragraph 0030). It is inherent that the primer has promoter sequence from bacteriophage T7.

In addition, as disclosed in the specification, the mRNA is faithfully amplified. It means that the amplification of the mRNA preserves either the total information content or the relative representation of the mRNAs in the population (See pg. 6, lines 14-17). Thus, the teachings of Pelletier et al. anticipate the limitations of claims 53, 56-57, 70-73, 76-77, and 79-80.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 54-55, 58, 67-69, 74-75, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelletier et al. (US 2002/0119467 A1, issued August 29, 2002).

The teachings of Pelletier et al. are set forth in section 2 above. Pelletier et al do not explicitly disclose the temperature at 42⁰C, the concentration of the primer no greater than 0.02uM, the concentration of the single-strand binding protein at least 0.0061mM or 0.015mM and the amount of total RNA not more than 100ng.

Pelletier et al disclose that the temperature of performing the RT is at 45⁰C and 55⁰C (See pg. 5, paragraph 0062). The amount of single binding protein used is 2ug (See pg. 6, paragraph 0064).

One of ordinary skill would have varied the reaction condition by optimizing the concentration of the single-strand binding protein, the temperature of the reaction and the amount primer and total RNA used to maximize the amount of transcription product as it was routine procedure to optimize reagent condition in assays. It would have been prima facie obvious to carry out the method for synthesizing cDNA with the temperature, and the amount of the single strand binding protein, primer and total RNA as recited in the claims.

WO 00/55307 is made of record as reference of interests because the reference teaches an improved method of cDNA synthesis in which the improvement is consisting in an addition of a RNA binding protein to the nucleic acid polymerization mixture comprising the reverse transcriptase to make full length of cDNA (See the Abstract).

Summary

5. No claims are allowable.

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6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung JT
April. 22, 2004


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/29/04